

OXOP-D EYE/EAR DROPS

DESCRIPTION

OXOP-D Eye/Ear Drops is a combination of Ofloxacin, a fluoroquinolone antimicrobial and dexamethasone, a potent corticosteroid.

COMPOSITION

Each ml of **OXOP-D Eye/Ear Drops** contains:

Ofloxacin IP	0.3% w/v
Dexamethasone sodium phosphate IP equivalent to Dexamethasone	0.1% w/v
Benzalkonium Chloride IP	0.01% w/v
Sterile aqueous base	qs

CLINICAL PHARMACOLOGY

Ofloxacin has *in vitro* activity against a broad range of gram-positive and gram-negative aerobic and anaerobic bacteria. It is bactericidal at concentrations equal to or slightly greater than inhibitory concentrations.

Ofloxacin is thought to exert a bactericidal effect on susceptible bacterial cells by inhibiting DNA gyrase, an essential bacterial enzyme that is a critical catalyst in the duplication, transcription, and repair of bacterial DNA.

Ofloxacin has been shown to be active against most strains of the following organisms both *in vitro* and clinically:

Aerobic Gram-Positive:

Staphylococcus aureus
Staphylococcus epidermidis
Streptococcus pneumoniae

Aerobic Gram-Negative:

Enterobacter cloacae
Haemophilus influenzae
Proteus mirabilis
Pseudomonas aeruginosa
Serratia marcescens
Moraxella catarrhalis
Escherichia coli

Anaerobic Species:

Propionibacterium acnes

Corticosteroids like **Dexamethasone** suppress the inflammatory response to a variety of agents. Since they may inhibit the body's defense mechanism against infection, a concomitant antimicrobial drug may be necessary when this inhibition is considered to be clinically significant.

The combination of Dexamethasone a potent corticosteroid and Ofloxacin a broad spectrum antibacterial in a topical formulation like **OXOP-D Eye/Ear Drops** will together effectively resolve inflammation and infection in severe eye conditions.

INDICATIONS

- **OXOP-D** is indicated for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where bacterial ocular infection or a risk of infection exists.
- **OXOP-D** is indicated in inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe where the inherent risk of steroid use in certain infective conjunctivitis is accepted to obtain a diminution in edema and inflammation.
- **OXOP-D** is also indicated in chronic anterior uveitis and corneal injury from chemical radiation, thermal burns, or penetration of foreign bodies, where the risk of infection is high or where there is an expectation that potentially dangerous numbers of bacteria will be present in the eye.

- **OXOP-D** is also indicated for the treatment of ear infections accompanied by inflammation such as otitis externa, acute and chronic otitis media. **OXOP-D** may be used postoperatively.

DOSAGE & ADMINISTRATION

For ocular conditions:

One or two drops instilled into the conjunctival sac every 4 to 6 hours.

During the initial 24 to 48 hours, the dosage may be increased to one to two drops every 2 hours. Frequency should be decreased gradually or warranted by improvement in clinical signs. Care should be taken not to discontinue therapy prematurely.

For otic conditions:

Instill 2-4 drops 3-4 times daily.

CONTRAINDICATIONS

The use of **OXOP-D Eye/Ear Drops** is contraindicated in patients with hypersensitivity to any ingredient of the formulation.

The use of **OXOP-D Eye/Ear Drops** is also contraindicated in epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, and in other viral diseases of the conjunctiva and cornea, mycobacterial infection of the eye and fungal diseases of ocular structures.

WARNINGS

OXOP-D Eye/Ear Drops solution should not be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye.

PRECAUTIONS

The prolonged use of antibiotics may occasionally result in overgrowth of nonsusceptible organisms, including fungi. If new infections appear the drug should be discontinued and appropriate measures instituted. In all serious infections the topical use of **OXOP-D Eye/Ear Drops** should be supplemented by appropriate systemic medication.

Prolonged use of **OXOP-D Eye/Ear Drops** may result in glaucoma and posterior subcapsular cataract formation. If these products are used for 10 days or longer, intra-ocular pressure should be routinely monitored even though it may be difficult in children and uncooperative patients.

Pregnancy

There are no adequate and well-controlled studies in pregnant women. **OXOP-D Eye/Ear Drops** should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation

It is not known whether topical administration of corticosteroids would result in sufficient systemic absorption to produce detectable quantities in human milk. It is also not known whether Ofloxacin is excreted in human milk following topical ophthalmic administration. Because many drugs are excreted in human milk, caution should be exercised when the combination is administered to a nursing woman.

Moreover, because of the potential of serious adverse reactions from Ofloxacin in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug taking into account the importance of the drug to the mother.

Pediatric Use:

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

Adverse effects have occurred with steroid/anti-infective combination drugs, which can be attributed to the steroid component, the anti-infective component, or the combination.

The most frequently reported drug-related adverse reactions seen with Ofloxacin are: transient ocular burning or discomfort. Other reported reactions include stinging, redness, itching, conjunctivitis/keratitis, periocular/facial edema, foreign body sensation, photophobia, blurred vision, tearing, dryness, and eye pain.

The reactions due to the steroid component are: elevation of intraocular pressure with possible development of glaucoma, and infrequent optic nerve damage, posterior subcapsular cataract formation and delayed wound healing.

PRESENTATION

OXOP-D Eye/Ear Drops is available in bottles of 10 ml